Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Oceanview Healthcare & Rehabilitation Center,
(CCN: 67-5743),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-15-789

Decision No. CR4569

Date: April 4, 2016

DECISION

Oceanview Healthcare & Rehabilitation Center (Oceanview or Petitioner) challenges the Centers for Medicare & Medicaid Services' (CMS) determination that it was not in substantial compliance with the Medicare program participation requirements that a skilled nursing facility (SNF) immediately consult with a resident's physician when the resident experiences a significant change in his physical condition, and provide necessary care and services to the resident. 42 C.F.R. §§ 483.20(b)(11), 483.25. Oceanview also challenges the imposition of two per-instance civil money penalties (CMPs) totaling $6,000, and the denial of payment for new admissions (DPNA) effective November 8, 2014, through January 8, 2015. For the reasons discussed below, I affirm CMS's determination.

I. Background

The Social Security Act (Act) sets forth requirements for an SNF's participation in the Medicare program and authorizes the Secretary of Health and Human Services (the Secretary) to promulgate regulations implementing those statutory provisions. 42 U.S.C. § 1395i-3. The Secretary's regulations are found at 42 C.F.R. Parts 483 and 488. To participate in the Medicare program, an SNF must maintain substantial compliance with

program participation requirements. To be in substantial compliance, an SNF's deficiencies may "pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." 42 C.F.R. § 488.301.

The Secretary contracts with state agencies to conduct periodic surveys to determine whether SNFs are in substantial compliance. 42 U.S.C. § 1395aa(a); 42 C.F.R. § 488.10. The Act also authorizes the Secretary to impose enforcement remedies against SNFs that are not in substantial compliance with the program participation requirements. 42 U.S.C. § 1395i-3(h)(2). The regulations specify the enforcement remedies that CMS may impose. 42 C.F.R. § 488.406. Among other enforcement remedies, CMS may impose a per-day CMP for the number of days an SNF is not in substantial compliance or a per-instance CMP for each instance of the SNF's noncompliance. 42 C.F.R. § 488.430(a). A per-day CMP may range from either $50 to $3,000 per day for less serious noncompliance, or $3,050 to $10,000 per day for more serious noncompliance that poses immediate jeopardy to the health and safety of residents. 42 C.F.R. § 488.438(a)(2). "Immediate jeopardy" exists when "the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. The authorized range for a per-instance CMP is $1,000 to $10,000. 42 C.F.R. § 488.438(a)(2).

If CMS imposes a CMP based on a noncompliance determination, then the facility may request a hearing before an Administrative Law Judge (ALJ) to challenge the noncompliance finding and enforcement remedy. 42 U.S.C. §§ 1320a-7a(c)(2), 1395i(h)(2)(B)(ii)); 42 C.F.R. §§ 488.408(g), 488.434(a)(2)(viii), 498.3(b)(13).

Oceanview is an SNF located in Texas City, Texas that participates in the Medicare and Medicaid programs. The Texas Department of Aging and Disability Services (survey agency) completed a combined recertification and complaint investigation survey at Petitioner's facility on October 11, 2014. CMS Exhibit (Ex.) 4. In an October 29, 2014 initial determination, CMS stated that, based on the October 11, 2014 survey, it found Petitioner was not in substantial compliance with seven program requirements, four of which were cited at a scope and severity level of "J," constituting immediate jeopardy to resident health and safety.[1] CMS Ex. 3 at 7. CMS determined that immediate jeopardy

[1] Scope and severity levels are used by CMS and state survey agencies when selecting remedies. The scope and severity level is designated by letters A through L, selected by CMS or the state agency from the scope and severity matrix published in the State Operations Manual, chap. 7, § 7400.5 (Sep. 10, 2010). A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm, which is an insufficient basis for imposing an enforcement remedy. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that

had been abated, but that Petitioner remained out of substantial compliance. The deficiencies cited were as follows:

1. 42 C.F.R. § 483.10(b)(11), F157 (Physician Consultation and Notification) at scope and severity (s/s) level J (immediate jeopardy);

2. 42 C.F.R. § 483.20(b)(2)(iii), F275 (Comprehensive Assessments) at s/s level D (no actual harm with the potential for more than minimal harm);

3. 42 C.F.R. § 483.20(g)-(j), F278 (Assessment Accuracy/Coordination/ Certification/Penalty for Falsification) at s/s level D;

4. 42 C.F.R. § 483.20(k)(3)(i), F281 (Comprehensive Care Plans) at s/s level J;

5. 42 C.F.R. § 483.25, F309 (Quality of Care) at s/s level J;

6. 42 C.F.R. § 483.70(h), F465 (Physical Environment) at s/s level E (no actual harm with the potential for more than minimal harm);

7. 42 C.F.R. § 483.75, F490 (Administration) at s/s level J.

CMS Ex. 3 at 7. CMS also found that Petitioner was out of compliance with the National Fire Protection Association's Life Safety Code, citing deficiencies under K021 (s/s level F, no actual harm with the potential for more than minimal harm), K025 (s/s level E), K038 (s/s level D), K067 (s/s level F), and K076 (s/s level D), which are violations of 42 C.F.R. § 483.70(a). CMS Ex. 3 at 7.

CMS advised Petitioner that it was imposing the following enforcement remedies: termination of Petitioner's provider agreement and participation in Medicare effective April 11, 2015, if Petitioner did not return to substantial compliance prior to that date; a per-instance CMP of $4,000 for the deficiency under 42 C.F.R. § 483.25; a per-instance CMP of $2,000 for the deficiency under 42 C.F.R. § 483.10(b)(11); a per-instance CMP of $2,000 for the deficiency under 42 C.F.R. § 483.20(k)(3)(i); and a DPNA effective November 8, 2014. CMS Ex. 3 at 7-9.

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presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L are deficiencies that constitute immediate jeopardy to resident health or safety. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency.

In a December 23, 2014 letter, CMS rescinded the $2,000 per-instance CMP for the alleged deficiency under 42 C.F.R. § 483.20(k)(3)(i). CMS also stated that the other remedies stated in the October 29, 2014 letter remained unchanged. CMS Ex. 3 at 14.

The survey agency completed a follow-up survey on December 18, 2014. CMS Ex. 37. By letter dated January 21, 2015, CMS notified Petitioner that CMS found Petitioner out of substantial compliance with 42 C.F.R. § 483.35(i) (F371, s/s level E) and 42 C.F.R. § 483.65 (F441, s/s level D). CMS advised Petitioner that the enforcement remedies remained unchanged. CMS Ex. 3 at 17.

By letter dated February 18, 2015, CMS notified Petitioner that it had returned to substantial compliance on January 9, 2015. CMS stated that it had revised the enforcement remedies as follows: the termination of Petitioner's provider agreement was rescinded; a DPNA was effective November 8, 2014, through January 8, 2015; a per-instance CMP remained imposed in the total amount of $6,000 (consisting of a per-instance CMP of $4,000 for the alleged deficiency under 42 C.F.R. § 483.25 and a per-instance CMP of $2,000 for the alleged deficiency under 42 C.F.R. § 483.10(b)(11), both from the October 11, 2014 survey). CMS Ex. 3 at 2.

On December 24, 2014, Petitioner requested a hearing to dispute CMS's finding that it was not in substantial compliance with program participation requirements and the imposition of remedies. Petitioner did not appeal the deficiencies cited from the December 18, 2014 revisit survey. *See* CMS Ex. 3 at 17. In response, I issued an Acknowledgment and Pre-hearing Order (Pre-hearing Order) establishing a schedule for filing briefs and pre-hearing exchanges.

In compliance with my pre-hearing order, the parties filed their pre-hearing exchanges. CMS submitted a pre-hearing brief (CMS Br.), accompanied by 38 proposed exhibits (CMS Exs. 1-38). Petitioner submitted a pre-hearing brief (P. Br.), accompanied by 18 exhibits (P. Exs. 1-18).

II. Decision on the Record

I admit all of the parties' proposed exhibits because neither party objected to any of them. Pre-hearing Order ¶ 7.

My Pre-hearing Order advised the parties that they needed to submit written direct testimony for any proposed witnesses. Pre-hearing Order ¶ 8. CMS offered the written direct testimony of four proposed witnesses: Misty Crawford, RN, a surveyor for the survey agency (CMS Ex. 32); Patricia O'Connor-Breaux, LBSW, a surveyor for the survey agency (CMS Ex. 33); Erin Smith, RD, a surveyor for the survey agency (CMS Ex. 34); and Susan LeBlanc, RN, a nurse consultant for CMS (CMS Ex. 35). Petitioner

offered the written direct testimony of one proposed witness, Tim Burningham, Petitioner's Administrator (P. Ex. 18). Although Mr. Burningham's declaration indicates that an Exhibit 1 was attached to it, no such document was attached. P. Ex. 18 at 3-4.

My Pre-hearing Order also advised that if an opposing party wanted to cross-examine a witness or witnesses for whom written direct testimony had been submitted, the opposing party had to affirmatively request to cross-examine the witness or witnesses. Pre-hearing Order ¶ 9. However, neither party requested to cross-examine any of the witnesses. As a hearing for the purpose of cross-examining witnesses "will be necessary only if a party files admissible, written direct testimony, and the opposing party asks to cross-examine," I issue this decision based on the written record. Pre-hearing Order ¶¶ 10, 13.

III. Issues

The issues presented are:

1. Whether Petitioner failed to be in substantial compliance with the Medicare program participation requirements at 42 C.F.R. §§ 483.10(b)(11) and 483.25.

2. If so, whether the $2,000 per-instance CMP for violating 42 C.F.R. § 483.10(b)(11) and the $4,000 per-instance CMP for violating 42 C.F.R. § 483.25 are reasonable, and whether CMS had a legitimate basis for imposing a DPNA from November 8, 2014, through January 8, 2015.

Although CMS and Petitioner both present arguments as to whether Petitioner was in substantial compliance with various deficiencies identified by CMS following the survey and follow-up survey, CMS ultimately only imposed CMPs based on deficiencies under 42 C.F.R. §§ 483.10(b)(11) and 483.25 (CMS Ex. 3). An SNF has a right to a hearing before an administrative law judge when CMS has "made an adverse 'initial determination' of a kind specified in 42 C.F.R. § 498.3(b)"; however, it is only after CMS makes a finding that an SNF is noncompliant **and** imposes a remedy under 42 C.F.R. § 488.406, that the SNF has received an initial determination subject to further review. 42 C.F.R. § 498.3(b)(13); *Columbus Park Nursing and Rehab. Ctr.*, DAB No. 2316, at 6 (2010); *see also* 42 C.F.R. §§ 488.330(e)(3), 488.408(g)(1), 498.3(a)(1), 498.3(a)(3)(ii). Consistent with this, an SNF "has no right to an ALJ hearing to contest survey deficiency findings where CMS has not imposed any of the remedies specified in section 488.406 based on those findings, or where CMS imposed, but subsequently rescinded, any such remedies." *Columbus Park*, DAB No. 2316, at 7. Therefore, I only have jurisdiction to adjudicate the alleged violations of 42 C.F.R. §§ 483.10(b)(11) and 483.25 from the October 11, 2014 survey because they are the only deficiencies for which CMS proposed enforcement remedies. Further, while CMS imposed a DPNA in this case without specifying a particular deficiency on which the DPNA was based, as explained below, any failure on Petitioner's part to be in substantial compliance is a basis for imposing a

DPNA. Because I conclude below that Petitioner was not in substantial compliance with 42 C.F.R. §§ 483.10(b)(11) and 483.25, CMS had a legitimate basis for imposing the DPNA. Therefore, it is unnecessary for me to consider any other deficiencies. *Perry Cty. Nursing Ctr. v. U.S. Dep't of Health & Human Servs.*, 603 F. App'x 265, 271 (5th Cir. 2015); *Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 847 (6th Cir. 2010).

IV. Findings of Fact

1. Resident 17 was an 84-year-old male at the time of the October 2014 survey. P. Ex. 2.

2. Resident 17 was admitted to Petitioner's facility on October 18, 2012, and was readmitted on June 6, 2014, from a hospital stay. P. Exs. 2, 3; CMS Ex. 5.

3. In 2014, Resident 17's diagnosed ailments included, among other things, muscular wasting and disuse atrophy, history of fall, depression, senile dementia with delusional features, hypertension, hyperlipidemia, coronary atherosclerosis, lack of coordination, atrial fibrillation, and Alzheimer's disease. P. Ex. 1 at 1; CMS Ex. 5 at 15-16.

4. Resident 17 was prescribed several medications, including Coumadin® and Plavix® as anticoagulant therapy, to address his atrial fibrillation and coronary atherosclerosis. P. Ex. 1 at 3; CMS Ex. 9 at 3-4; CMS Ex. 14 at 1, 3-4, 8.

5. Resident 17 was significantly limited in his mobility, used a wheelchair, and required extensive assistance with almost all activities of daily living. CMS Ex. 5 at 12, 13.

6. Resident 17 had a fall in the month prior to his readmission and had two falls since his readmission, but had not experienced any injuries. CMS Ex. 5 at 19.

7. At the time of Resident 17's re-admission, Petitioner's staff initiated a fall risk evaluation and determined that he was at "high risk" for falls. P. Ex. 5 at 1. A care plan document initiated on October 31, 2013, noted that he was at risk for falls related to his impaired mobility and dementia. P. Ex. 4 at 6. His care plan contained the following interventions to prevent fall or injury: have commonly used articles within easy reach; transfer and change positions slowly; reinforce the need to call for assistance; proper and nonslip footwear; two side rails up at all times/when in bed for safety; ensure environment is free of clutter; pay attention to his attempt to communicate needs; and orient resident to his environment each time changes are made. P. Ex. 4 at 6.

8. Resident 17 fell on August 30 and 31, 2014. P. Ex. 6 at 1, 3. On both occasions, he denied having any pain and an examination revealed that he had no injuries. The nurse notified the nurse practitioner of his falls via telephone; no new orders were given. P. Ex. 6 at 1, 3. After Resident 17's falls, Petitioner's staff updated his care plan on September 2, 2014, and included the following interventions: put to bed as soon as possible after meals to prevent self-transferring; put bed in the lowest position; perform neuro-checks as ordered; and continue interventions on the at-risk plan. P. Ex. 4 at 2.

9. Just prior to September 20, 2014, Resident 17's daily dose of 3 mg Coumadin® had been on placed on hold for five days per his physician's orders. CMS Ex. 11 at 2-3; *see* CMS Ex. 14 at 1, 3.

10. On September 20, 2014, around 7:00 p.m., a nurse found Resident 17 lying on the floor next to his bed with approximately 60 cc of dark red fluid on the floor. P. Ex. 6 at 7-8; CMS Ex. 10; CMS Ex. 15 at 5.[2] There were no witnesses to describe what occurred. Resident 17 sustained a 1 cm x 1 cm by 1 cm laceration above his right eyebrow. He was alert, oriented, and able to communicate; he denied being in pain. When asked what happened, the resident stated that "[he] was trying to get up." The nursing staff assessed Resident 17 and obtained his vital signs; cleaned, dried, and dressed the laceration; and assisted him back to bed. Neurological checks were initiated. Staff notified Resident 17's physician and the nurse practitioner of the fall, and they received new orders for the placement of a low bed, bed alarm, floor mat, and to continue to hold Coumadin®.[3] P. Ex. 6 at 8; CMS Ex. 10; *see* CMS Ex.

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[2] P. Ex. 6 at 7-8 and CMS Ex. at 15 at 5 are the same progress note documenting Resident 17's fall on September 20, 2014, and the treatment provided to Resident 17. Although the progress note is dated "9/21/2014" at "05:13," it is evident that the note relates to Resident 17's September 20, 2014 fall incident.

[3] There appears to be conflicting information in the record as to whether Petitioner's staff contacted Resident 17's physician after the resident fell. According to the SOD, when interviewed by the surveyor, the nurse stated that she reported the fall to the nurse practitioner, who did not order that the resident be sent to the hospital. CMS Ex. 4 at 4-5. The nurse did not state that she notified the resident's physician. However, Petitioner's progress note pertaining to the fall incident states "Dr. Alkarra [Resident 17's physician], NP Erin notified N.O. [new order] for low bed bed [sic] alarm and floormat and continue to hold coumadin resident resting stable . . . ." P. Ex. 6 at 8. The report prepared by Petitioner's staff following Resident 17's fall also indicated that the physician had been notified. CMS Ex. 10 at 1. It is not necessary for me to resolve this inconsistency in the record because whether or not Petitioner's staff notified Resident 17's physician after he fell on September 20, 2014, is not in issue.

14 at 3. Staff also notified Resident 17's relative, who was his durable power of attorney, of the incident. P. Ex. 6 at 8; CMS Ex. 10.

11. Throughout the night, Petitioner's nursing staff monitored Resident 17 and conducted neurological checks, documenting the findings on a neurological assessment form. P. Ex. 9 at 1; CMS Ex. 13. In addition to noting Resident 17's vital signs, the nurse documented the following as part of the assessment: level of consciousness, movement, hand grasps, pupil size, pupil reaction, and speech. P. Ex. 9 at 1; CMS Ex. 13. The nurse conducted the first neurological check at 7:00 p.m., and thereafter, conducted checks at 7:15 p.m., 7:30 p.m., 7:45 p.m., 8:15 p.m., 8:45 p.m., 9:15 p.m., 9:45 p.m., 10:45 p.m., 11:45 p.m., 12:45 a.m. (September 21, 2014), 4:45 a.m., 8:45 a.m., and 12:45 p.m.[4] P. Ex. 9 at 1; CMS Ex. 13.

12. From 7:00 p.m. on September 20, 2014 through 4:45 a.m. on September 21, 2014, the nurse documented that Resident 17's neurological checks were normal – he was fully conscious, able to move all extremities, his hand grasps were strong, his speech was clear, and pupil reaction in both eyes was brisk. The nurse noted that, in both eyes, the pupils measured 3 mm. P. Ex. 9 at 1; CMS Ex. 13. At 8:45 a.m. on September 21, 2014, the nurse documented that Resident 17's pupils measured 4 mm. The resident did not exhibit any other neurological changes. The nurse did not notify Resident 17's physician of the increase in the resident's pupil size. Four hours later, at 12:45 p.m., the nurse again documented that Resident 17's pupils measured 4 mm. The resident did not exhibit any other neurological changes. Neither the nurse nor anyone else on Petitioner's staff notified Resident 17's physician of the increase in the resident's pupil size. P. Ex. 9 at 1; CMS Ex. 13.

13. Around 3:51 p.m., staff found Resident 17 unresponsive in his room.[5] P. Ex. 6 at 6; CMS Ex. 15 at 1, 12; *see* CMS Ex. 12. The resident did not respond to a

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[4] On the neurological assessment form, Petitioner's staff continued to write in the date "9/20" instead of writing "9/21" beginning with the 12:45 a.m. neurological check. P. Ex. 9 at 1; CMS Ex. 13. Both a nurse and the Director of Nursing (DON), when questioned by the surveyors, stated that the date should have been changed to "9/21." CMS Ex. 4 at 7, 48.

[5] Petitioner's records show that its staff found Resident 17 unresponsive at 3:51 p.m. on September 21, 2014. CMS Ex. 15 at 1, 12. However, the record also shows that Resident 17's physician gave the verbal order for Resident 17 to be sent to the hospital at 3:34 p.m. on September 21, 2014. CMS Ex. 7 at 7. Given that both parties consistently

sternum rub. Because he was gurgling, staff turned him on his right side. Resident 17 vomited a large amount of brown fluid with two small blood clots. Staff notified the resident's physician, who ordered that the resident be sent out via 911. EMS arrived and transported Resident 17 to the local hospital. P. Ex. 6 at 6; CMS Ex. 15 at 1, 12; *see* CMS Ex. 7 at 7; CMS Ex. 12. Staff also notified the resident's responsible party. P. Ex. 6 at 6; CMS Ex. 15 at 1.

14. Resident 17 died on September 23, 2014. His primary cause of death was "intracranial hemorrhage/subdural hematoma" and the secondary cause of death was "coagulopathy related to Coumadin." CMS Ex. 4 at 4, 22; P. Br. at 7; *see* CMS Ex. 26.

15. On September 22, 2014, at 1:55 p.m., Petitioner's DON notified the survey agency of Resident 17's fall and unresponsive state, and completed a Provider Investigation Report on September 24, 2014. CMS Ex. 11.

16. The DON indicated in the report that Resident 17 had suffered an unwitnessed injury of unknown origin at 7:00 p.m. on September 20, 2014. CMS Ex. 11 at 1. She notes that the resident had minimal functional ability; required no special supervision; was not independently ambulatory; was interviewable; did not have the capacity to make informed decisions; and was not wearing a Wanderguard at the time of the incident. CMS Ex. 11 at 1. The report states further that the resident was found unresponsive on September 21, 2014, at 3:51 p.m. and was transferred that day to the emergency room of the local hospital. CMS Ex. 11 at 2. The DON's description of what occurred on September 20 and September 21 and of Resident 17's condition is consistent with that given in the progress notes described above. CMS Ex. 11 at 2, 5. In listing the actions the facility took post-investigation, the report states that staff were "in-serviced to transfer residents on anticoagulant therapy to the emergency room for evaluation" and were "in-serviced to call 911 for acute changes in resident's condition." CMS Ex. 11 at 3.

V. Conclusions of Law and Analysis

1. Petitioner was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) because Petitioner failed to immediately consult with Resident 17's physician when Resident 17 experienced a significant change in his neurological status in the hours following a fall.

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reference "3:51 p.m." as the time the resident was found unresponsive, it is not necessary for me to reconcile any discrepancy regarding the times.

CMS asserts that Petitioner failed to be in substantial compliance with 42 C.F.R. § 483.10(b)(11) with regard to Resident 17. Specifically, CMS claims that, based on interviews and record review, Petitioner failed to consult with Resident 17's physician regarding the resident's anticoagulant and antiplatelet medications when he fell and injured himself on September 20, 2014. CMS also alleges that Petitioner failed to consult the physician when the resident had a change in condition at 8:45 a.m. the next morning, September 21, 2014. CMS Ex. 4 at 2.

The regulation entitled "Resident rights" requires:

> (b)(11) *Notification of changes*. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal respresentative (sic) or an interested family member when there is –
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> > (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
> > (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
> > (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
> > (D) A decision to transfer or discharge the resident from the facility as specified in § 483.12(a).

42 C.F.R. § 483.10(b)(11)(i).

The requirement to consult with a resident's physician is not discretionary and requires more than merely informing or notifying the physician. The preamble to the final rule reflects the Secretary's intention that the facility should "inform" the resident of the changes that have occurred but must "consult with the physician about actions that are needed." 56 Fed. Reg. 48,826, 48,833 (Sept. 26, 1991). Consultation implies the requirement for a dialogue with and a responsive directive from the resident's physician as to what actions are needed. The use of the term "immediately" in the regulation indicates that consultation is expected to be done as soon as the change is detected, without any intervening interval of time. The preamble to the final rule indicates that originally the proposed rule granted the facility up to 24 hours in which to consult with the resident's physician and to notify the legal representative or family. However, after

the receipt of comments stating that time is of the essence in such circumstances, the final rule amended that provision to require that the physician be consulted and the legal representative or family be notified immediately. 56 Fed. Reg. at 48,833. The point of using the word "immediately" recognized that in such situations a delay could result in a situation where a resident is beyond recovery or dies. Consultation with a physician must occur immediately, that is, without delay, after a significant change is detected or observed. *See Magnolia Estates Skilled Care*, DAB No. 2228, at 9 (2009).

Petitioner does not deny that its nursing staff did not immediately consult Resident 17's physician after discovering during an assessment that the resident's pupils had increased in size. P. Br. at 6, 13. In its defense, Petitioner argues that its staff properly monitored Resident 17's neurological condition in accordance with its policy and procedure for neurological evaluations following an incident involving head trauma. Moreover, Petitioner questions whether the increase in the resident's pupil size actually constituted a significant change in condition that triggered the consultation requirement of 42 C.F.R. § 483.10(b)(11)(i). P. Br. at 13. Petitioner argues that, because the resident did not exhibit other signs or symptoms of neurological or clinical compromise, the fact that his pupils slightly increased in size did not constitute a significant change in his status.

Petitioner's policy and procedure for neurological evaluations following an incident involving head trauma required staff to conduct a comprehensive neurological assessment for a minimum of 72 hours and document all observations on a neurological assessment form. CMS Ex. 18. The policy stated that "[t]he first examination of the resident is important to establish a baseline for future assessments. Any resident having an injury involving the head or an unobserved fall will have neuro checks and vital signs taken at least every eight (8) hours for twenty-four (24) hours or per specific facility, policy or physician's order." CMS Ex. 18. Petitioner's policy required staff to conduct assessments at specified intervals and document vital signs, responsiveness, level of consciousness, speech ability, motor ability, pupil signs, changes in condition, and any other pertinent observations. CMS Ex. 18. With respect to pupil signs, the policy stated:

> A. Look at pupils and compare size and equality.
> B. [U]sing an overhead light, simultaneously compare the size of the pupils and their reaction to light.
> C. If a flashlight is used, shine directly into eye being examined while other eye is covered.

CMS Ex. 18 at 2. Petitioner's staff documented all observations from Resident 17's neurological checks on a neurological assessment form, as required by Petitioner's policy. Although Petitioner's policy does not state when a resident's physician should be consulted, the neurological assessment addresses this with an emphatic directive at the bottom of the form: "Notify MD IMMEDIATELY of signs and symptoms of Intracranial Pressure!!!" CMS Ex. 13. This is consistent with Petitioner's policy on the subject of

"Monitoring for Significant Change in Condition." CMS Ex. 19. Among the directives, the policy instructs "[p]hysician, resident, and responsible party will be notified of the significant change." CMS Ex. 19 at 2.

After Resident 17 fell on September 20, 2014, Petitioner's nurse conducted the first neurological check at 7:00 p.m. At that time, Petitioner's nurse documented that both of his pupils measured 3 mm in size. Because these measurements were taken during the initial neurological check, they became part of Petitioner's "baseline for future assessments." *See* CMS Ex. 18 at 1. From 7:00 p.m. on September 20, 2014, through 4:45 a.m. on September 21, 2014, the neurological checks conducted by Petitioner's nurse showed that Resident 17 did not exhibit any abnormal neurological signs and his pupils remained at 3 mm. However, at 8:45 a.m. on September 21, 2014, the nurse documented that Resident 17's pupils measured 4 mm. P. Ex. 9 at 1; CMS Ex. 13. Four hours later, at 12:45 p.m., the nurse again noted that Resident 17's pupils measured 4 mm. P. Ex. 9 at 1; CMS Ex. 13. Despite documenting the increased pupil size during two separate assessments, the nurse did not consult Resident 17's physician regarding this change in his neurological status. It was not until Petitioner's staff found the resident unresponsive in his room around 3:51 p.m. that they finally consulted his physician, who ordered that the resident be sent to the hospital.

Petitioner's defense that Resident 17's increased pupil size, without other signs or symptoms of neurological compromise, did not constitute a significant change in condition is without merit. The objective behind performing the neurological checks was so that staff could monitor Resident 17 at regular intervals for <u>any</u> signs of deterioration in his condition. Any deviations from his baseline measurements, including changes in pupil size and reaction, could be an indication of a potentially life-threatening condition. Even in the absence of other clinical changes, the increase in Resident 17's pupil size, in and of itself, was a possible sign that he was no longer within normal limits neurologically, specifically, that he may be experiencing intracranial pressure. In the SOD, the relationship between pupil size and intracranial pressure is stated as follows:

> Changes in pupil size, equality, and reaction to light, and extraocular movements are indicative of compression of the third, fourth, and sixth cranial nerves. Assessment of these changes should be as accurate and objective as possible. Unilateral and bilateral evaluations are important and usally [sic] are recorded by a drawing of the actual size of each pupil or by precise measurements using a small metric ruler.

CMS Ex. 4 at 7, quoting http://medical-dictionary.thefreedictionary.com. Susan LeBlanc, RN, a nurse with over 30 years of experience, testified consistent with this definition that "[i]ntracranial pressure is manifested by change in pupil size, equality and reaction to light." CMS Ex. 35 at 1, 3.

Although Petitioner argues that an online dictionary should not be considered as valid authority on the topic of intracranial pressure, it did not offer any other authoritative texts or medical expert testimony on the topic. In fact, in its pre-hearing brief, Petitioner concedes that "a 1 mm change in pupil size *may be* a sign consistent with intracranial pressure." P. Br. at 13-14 (emphasis in original). Further, Petitioner's policy on neurological assessments specifically tells its staff to "[l]ook at pupils and compare size and equality," showing that Petitioner understood the importance in changes in pupil size as described in the excerpt from the on-line medical dictionary quoted in the SOD. CMS Ex. 18 at 2. Consistent with this understanding, Petitioner's DON admitted, in an interview with a surveyor, that Resident 17's change in pupil size from 3 mm to 4 mm warranted physician notification. CMS Ex. 4 at 7. Implicit in the DON's statement is the recognition, consistent with Petitioner's own admission, that the resident's increased pupil size should not have been ignored because it was possibly indicative of a serious neurological complication.

Moreover, in attempting to minimize the change in Resident 17's pupil size as isolated and insignificant, Petitioner fails to take into account that Resident 17 had fallen around 7:00 p.m. the previous evening and hit his head, and that Resident 17 was taking Plavix® therapy (75 mg. daily) at the time of his fall, which increased his risk of developing possible complications. CMS Ex. 14 at 8. In fact, following the fall, Petitioner continued to administer Plavix®; however, as Misty Crawford, RN testified, doing so "is contraindicated when someone has an intracranial hemorrhage and increases the risk of bleeding." CMS Ex. 32 at 3. Further, Resident 17's physician had ordered that his Coumadin® be held from September 15 through September 20, 2014 because of his elevated PT/INR (prothrombin time/international normalized ratio) lab results. CMS Ex. 7, at 8, 9, 20, 22; CMS Ex. 14, at 1, 3; *see* CMS Ex. 8 at 1, 2. CMS notes, and Petitioner does not dispute, that the PT/INR test evaluates the ability of blood to clot properly. CMS Br. at 3 nn.2-3. Therefore, the fall and Resident 17's medication history, which presented the possibility that Resident 17 could not properly clot, should have resulted in extreme vigilance for an intracranial bleed. *See* CMS Ex. 35 at 3 ("The resident's primary [care] physician was also the facility Medical Director who stated 'if a resident hit their head and had a high INR (international normalized ratio – a measurement of Coumadin effectiveness) he should have been sent out. That's the standard.'"); *Cf. Autumn Care of Norfolk*, DAB CR1017 (2003) (quoting testimony of a physician stating that "[t]he Coumadin really is a signal . . . to physicians and nursing staff that any, even slight fall, could result in a significant and possibly fatal intracranial bleed."). Based on the total picture presented by these facts, it is clear that Resident 17's increased pupil size was potentially an indicator of a life-threatening complication that warranted immediate physician consultation and intervention. Without immediate physician intervention, Petitioner's staff had no way of knowing with any certainty whether Resident 17's increased pupil size was as insignificant as it claims it was.

I note further that neither Petitioner's policy on neurological evaluations nor its neurological assessment form contains any requirement that staff must first identify a combination of symptoms before consulting a physician of a change in condition. That the observation of even a single change in condition was sufficient to trigger Petitioner's duty to immediately consult the resident's physician is underscored by Petitioner's directive to its staff: "Notify MD IMMEDIATELY of signs and symptoms of Intracranial Pressure!!!" CMS Ex. 13.

When the nurse discovered that Resident 17's pupils had increased by 1 mm at 8:45 a.m. on September 21, 2014, this significant change in condition should have triggered the staff's duty to immediately notify and consult with his physician. Under 42 C.F.R. § 483.10(b)(11), a facility has the obligation to consult immediately with a resident's physician in any situation where "there is a chance that physician intervention is needed." *Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 844 (2010). However, rather than notifying Resident 17's physician immediately, Petitioner's nursing staff failed to recognize or chose to ignore this potentially life-threatening change in his condition for hours. After seven hours had elapsed from the time his increased pupil size was first discovered at 8:45 a.m., Resident 17 became unresponsive. It took such an obvious indication to move Petitioner's staff to action. However, by this point, it was too late. Petitioner thus failed to fulfill its regulatory duty to immediately consult Resident 17's physician when, based on all of the facts surrounding this case, Petitioner identified a significant change in Resident 17's neurological condition.

The SOD makes the additional allegation that Petitioner contravened the physician notification requirement when it "failed to consult with the physician regarding anticoagulant and antiplatelet use when Resident #17 had a fall with injury on 9/20/14." CMS Ex. 4 at 2. According to the SOD, a nurse failed to review all of Resident 17's medications with his physician after his fall incident to determine whether the resident's Plavix® should be held. CMS Ex. 4 at 3. Petitioner asserts that it was not necessary for Petitioner's nursing staff to specifically consult with Resident 17's physician on the matter of whether Plavix® should have been held because the physician would have known what medications he had prescribed for Resident 17. P. Br. at 12-13. However, CMS did not include an argument in its brief to support this additional allegation as an independent basis to uphold a violation of 42 C.F.R. § 483.10(b)(11)(i). CMS Br. at 3-4, 7. Therefore, I consider CMS to have abandoned that allegation from the SOD in this proceeding.

2. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 because, based on its failure to immediately consult with Resident 17's physician when the resident experienced a significant change in condition, Petitioner failed to provide the necessary care and services to Resident 17.

In the SOD, the allegations of Petitioner's noncompliance with 42 C.F.R. § 483.25 are based on the same facts relating to Resident 17 discussed above regarding the violation of 42 C.F.R. § 483.10(b)(11). CMS Ex. 4 at 42-63. CMS contends that Petitioner failed to provide the necessary care and services to Resident 17 by failing to notify his physician immediately when he exhibited a change in condition on September 21, 2014, and by failing to review his medications with his physician after his September 20, 2014 fall to determine if his Plavix® should be held. CMS Ex. 4 at 43.

The quality of care regulation at 42 C.F.R. § 483.25 requires that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." An SNF's failure to provide necessary care and services under 42 C.F.R. § 483.25 can be evidenced by a facility's failure to immediately notify a resident's physician when the resident has experienced a significant change in condition. *Magnolia Estates*, DAB No. 2228, at 19-21 ("Failure to notify a physician about a clinical condition that required immediate physician consultation and intervention in order to mitigate a risk of infection and more serious physical injury is clearly a failure to provide 'necessary care and services' to ensure that a resident attains or maintains her highest practicable well-being.").

As previously discussed in detail above, Resident 17 experienced a significant change in his neurological condition on the morning of September 21, 2014, when a neurological check showed that his pupils had increased in size from his baseline measurement of 3 mm to 4 mm. However, Petitioner's staff failed to immediately notify Resident 17's physician about this change in his status, which was a possible sign of intracranial pressure. When Resident 17 continued to exhibit increased pupil size four hours later, Petitioner's staff again failed to properly respond to this change in his condition and failed to notify his physician. As the record shows, it was not until Resident 17 was found unresponsive in his room over seven hours later that his physician was finally notified, and the resident was sent to the hospital.

In order to carry out its regulatory duty to provide the necessary care and services to Resident 17, it was crucial for Petitioner's staff to monitor him for any significant clinical changes after he fell and consult immediately with his physician upon the discovery of any such signs. Petitioner's failure to immediately notify Resident 17's physician about the resident's increased pupil size deprived him of potentially life-saving care and services, in violation of 42 C.F.R. § 483.25.

As for CMS's allegation that Petitioner's staff did not review all his medications with Resident 17's physician after his fall, CMS did not argue this point in its brief and, as explained above, I consider that allegation to have been abandoned as a basis for a violation of 42 C.F.R. § 483.25. CMS Br. at 3-4, 6.

3. CMS's finding of immediate jeopardy is not reviewable in this forum.

Petitioner has challenged CMS's determination that the deficiencies cited under 42 C.F.R. §§ 483.10(b)(11)(i) and 483.25 placed Resident 17 in immediate jeopardy. However, because CMS has imposed only per-instance CMPs in this case, I have no authority to review CMS's immediate jeopardy determination.

An ALJ may review CMS's scope and severity findings (which includes a finding of immediate jeopardy) only if a successful challenge would affect: (1) the range of the CMP amounts that CMS could collect; or (2) a finding of substandard quality of care that results in the loss of approval of a facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14), (d)(10)(i)-(ii).[6] Petitioner's challenge meets neither of these regulatory criteria.

In this case, CMS imposed two per-instance CMPs. Unlike per-day CMPs, under the regulations, there is only a single range for a per-instance CMP, which is $1,000 to $10,000, and this range applies to both immediate jeopardy and non-immediate jeopardy level deficiencies. *Compare* 42 C.F.R. § 488.438(a)(1) *with* 42 C.F.R. § 488.438(a)(2). Consequently, because CMS only imposed per-instance CMPs against Petitioner, a successful challenge to the immediate jeopardy finding would not affect the range of CMP amounts that CMS could collect. *NMS Healthcare of Hagerstown,* DAB No. 2603, at 6-7 (2014). Moreover, Petitioner has not shown that it operates a nurse aide training program that could be affected. For these reasons, Petitioner has no right to appeal the immediate jeopardy determination.

4. A per-instance CMP of $2,000 is a reasonable enforcement remedy for Petitioner's noncompliance with 42 C.F.R. § 483.10(b)(11) and a per-instance CMP of $4,000 is a reasonable enforcement remedy for Petitioner's noncompliance with 42 C.F.R. § 483.25.

I have concluded that Petitioner violated 42 C.F.R. §§ 483.10(b)(11) and 483.25. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. Here, CMS has chosen to impose two per-instance CMPs

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[6] "Substandard quality of care" is identified by the situation where there are one or more deficiencies related to participation requirements under 42 C.F.R. §§ 483.13 (Resident Behavior and Facility Practices), 483.15 (Quality of Life), or 483.25 (Quality of Care), which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm. 42 C.F.R. § 488.301.

based on its failure to be in compliance with each of the program participation requirements identified above. As discussed below, I find the CMP amounts to be reasonable.

In determining whether the per-instance CMP amounts imposed against Petitioner are reasonable, I apply the factors listed in 42 C.F.R. § 488.438(f). 42 C.F.R. § 488.438(e)(3). These factors include: (1) the facility's history of compliance; (2) the facility's financial condition; (3) the factors specified at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort, or safety. The absence of culpability is not a mitigating factor. The factors at 42 C.F.R. § 488.404 include: (1) the scope and severity of the deficiency; (2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and (3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

CMS proposed a per-instance CMP of $2,000 for the noncompliance with 42 C.F.R. § 483.10(b)(11) (F157) and a per-instance CMP of $4,000 for the noncompliance with 42 C.F.R. § 483.25 (F309). Petitioner challenged the reasonableness of the proposed CMP amounts in its hearing request.

I have received no evidence of prior noncompliance, and Petitioner has not offered any evidence showing an inability to pay the relatively small per-instance CMPs. Unless a facility contends that a particular regulatory factor does not support the CMP amount, an ALJ must sustain it. *Coquina Ctr.*, DAB No. 1860 (2002).

In examining the seriousness of the deficiency, I find that Petitioner's failure to consult Resident 17's physician when he exhibited a significant change in his neurological status placed him at risk for serious harm. It was Petitioner's duty to monitor Resident 17's neurological status following his fall, and immediately consult his physician if he showed any significant change in his condition. Petitioner's staff, however, failed to recognize or ignored Resident 17's increased pupil size, which was a sign of a potentially life-threatening condition, and made no attempt to notify his physician until over seven hours later, when the resident was found unresponsive. Petitioner is thus culpable for its staff's inaction and its failure to provide the necessary care and services that Resident 17 required. I conclude based on my review of all the required factors, that the per-instance CMPs, which are in the lower half of the per-instance CMP range, are reasonable for Petitioner's noncompliance with Medicare requirements. *See* 42 C.F.R. §§ 488.408(d)(iv), 488.438(a)(2).

5. CMS had a legitimate basis to impose a DPNA from November 8, 2014 through January 8, 2015, because Petitioner was noncompliant with 42 C.F.R. §§ 483.10(b)(11) and 483.25, and I do not have authority to reverse that decision.

Petitioner asserts that CMS had no basis to impose a DPNA in this case. However, CMS may impose a DPNA any time there is a breach of substantial compliance. 42 C.F.R. § 488.417(a); *see Ridgecrest Healthcare*, DAB No. 2598 (2014) (holding that "42 C.F.R. § 488.417(a)[] authoriz[es] a DPNA when a facility is not in substantial compliance with the participation requirements"). Petitioner did not appeal the deficiencies cited from the December 18, 2014 revisit survey. *See* CMS Ex. 3 at 17. Therefore, I conclude that Petitioner has waived any dispute of the deficiencies cited from that survey. Petitioner has otherwise offered no evidence to establish that it returned to substantial compliance with program participation requirements prior to January 9, 2015, the date determined by CMS. Based on the violations of 42 C.F.R. §§ 483.10(b)(11) and 483.25, CMS had a legitimate basis to impose a DPNA, and I have no authority to reverse that discretionary decision. 42 C.F.R. § 498.3(c)(13).

6. Other issues raised by Petitioner are without merit in this case.

Petitioner notes that the survey agency conducted a survey of its facility on September 23, 2014, which focused on Resident 17 and his fall event of September 20, 2014, and found no deficiencies. Petitioner argues that CMS is thus procedurally precluded from revisiting those same facts and circumstances at the October 11, 2014 survey and concluding that immediate jeopardy existed based on "the same patient, the same fall, and the same Facility practices which were reviewed previously . . . on September 23, 2014." P. Br. at 9.[7]

I am not persuaded by Petitioner's argument. Petitioner cites no law or regulation in support of its position that CMS was prohibited from finding deficiencies related to the care of Resident 17 at the October 11, 2014 survey because the same information had been reviewed and resulted in no citations at the September 20 survey. Contrary to what Petitioner argues, nothing in the regulations precludes CMS or the state from re-evaluating information during a survey that may have already been reviewed at a prior survey. Nor do the regulations prohibit CMS from arriving at a different conclusion at a later survey as to Petitioner's noncompliance based upon its revisiting of a facility's records. Further, I find that the SOD from the October 11, 2014 survey adequately notified Petitioner of the factual bases for the deficiencies under F157 and F309, and

[7] The record shows that the survey agency received two separate complaints regarding the care and services provided to Resident 17, both of which related to his September 20, 2014 fall, and, in response to these complaints, the survey agency conducted a survey on September 23, 2014, and a survey on October 11, 2014 (which was part of the annual survey). CMS Exs. 31, 38. Although no deficiencies were cited at the September 23, 2014 survey, the October 11, 2014 survey resulted in citations at the immediate jeopardy level relating to Petitioner's care of Resident 17.

thus, Petitioner had adequate notice of what to defend. Even were I to agree with Petitioner that CMS's actions were "inconsistent" (P. Br. at 9), the evidence would still support my conclusion that Petitioner was not in substantial compliance with 42 C.F.R. §§ 483.10(b)(11) and 483.25.

VI. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with 42 C.F.R. §§ 483.10(b)(11) (F157) and 483.25 (F309). Further, I conclude that a per-instance CMP of $2,000 for noncompliance with 42 C.F.R. § 483.10(b)(11); a per-instance CMP of $4,000 for noncompliance with 42 C.F.R. § 483.25; and a DPNA effective November 8, 2014 through January 8, 2015, are reasonable enforcement remedies.

/s/
Scott Anderson
Administrative Law Judge